K102317

MAY 17 2011

510(k) Summary
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11-May-11

SleepNet Corporation
5 Merrill Industrial Drive
Hampton, NH 03842
Tel - 603-758-6625
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Official Contact: Jennifer Kennedy – Director of Quality

Proprietary or Trade Name: IQ® Ventilation Nasal Mask

Common/Usual Name: Patient interface

Classification Code/Name: BZD – accessory to non-continuous ventilator (respirator)
CFR 868.5895

Device: IQ® Ventilation Nasal Mask

Predicate Devices: K021534 – SleepNet IQ® Nasal mask
K063806 – SleepNet MoJo Full Face mask
K991648 – Respironics – Contour nasal mask (Deluxe)

Device Description:
The SleepNet IQ® Ventilation Nasal mask is a standard type nasal mask but with no vent ports in the swivel elbow which allows this mask to be used with CPAP and bi-level positive pressure systems.

The IQ® Ventilation Nasal mask requires that the mask and circuit be connected to a positive pressure (CPAP / bi-level) system with its own exhalation valve having adequate alarms and safety systems for positive pressure delivery failure.

The IQ® Ventilation Nasal mask also utilizes standard headgear, swivel elbow (without vent holes) and a delivery tube.

Indications for Use:
The IQ® Ventilation Nasal Mask is to be used as an accessory to CPAP / bi-level positive pressure systems that have adequate alarms and safety systems for positive pressure delivery failure. Use of this product is indicated for use with CPAP / BI-LEVEL POSITIVE PRESSURE SYSTEMS CONTAINING EXHALATION VALVES.

Patient Population: Adult patients (>30 kg)

Environment of Use: Home or hospital / institutional environments.

	Predicate SleepNet MoJo Non-vented Full face mask K063806	**Predicate SleepNet IQ® Nasal mask K021534**	**Predicate Respironics – Contour nasal mask (Deluxe) – K991648**	**Proposed SleepNet IQ® Ventilation Nasal mask**
Indications for Use	Accessory to ventilators that have adequate alarms and safety systems for ventilator failure and which are intended to administer positive pressure ventilation for treatment of respiratory failure or respiratory insufficiency.	Intended to be used with positive airway pressure devices such as CPAP operating at or above 3 cmH_2O for the treatment of adult OSA	Intended to be used with positive airway pressure devices such as CPAP or bi-level systems	Intended to be used with positive airway pressure devices such as CPAP or bi-level systems
Patient population	Adults >30 kg	Adults >30 kg	Adults >30 kg	Adults >30 kg
Environment of use	Hospital Institutional Home	Hospital Institutional Home	Hospital Institutional Home	Hospital Institutional Home
Single Patient, multi-use	Yes	Yes	Yes)Deluxe model)	Yes
Multi-patient, reusable	Yes	No	Yes	Yes
Vent ports	No	Yes	No	No
Equipment to which attached	Positive pressure ventilators with exhalation valves	CPAP	CPAP / bi-level Positive pressure systems with exhalation valves in circuit or system	CPAP / bi-level Positive pressure systems with exhalation valves in circuit or system

	Predicate SleepNet MoJo Non-vented Full face mask K063806	**Predicate SleepNet IQ® Nasal mask K021534**	**Predicate Respironics – Contour nasal mask (Deluxe) – K991648**	**Proposed SleepNet IQ® Ventilation Nasal mask**
Comparative Performance Testing				
Unintentional leak	5 cm H_2O – 5.8 lpm 15 cm H_2O – 9.5 lpm 30 cm H_2O – 14.2 lpm	N/A This model has vent holes	3 cm H_2O – 2.3 lpm 10 cm H_2O – 5.4 lpm 20 cm H_2O – 9.6 lpm 30 cm H_2O – 15.9 lpm 40 cm H_2O – 25.9 lpm	3 cm H_2O – 1.8 lpm 10 cm H_2O – 4.3 lpm 20 cm H_2O – 7.9 lpm 30 cm H_2O – 13.7 lpm 40 cm H_2O – 22.9 lpm
Intentional leak		N/A This model has vent holes	3 cm H_2O – 1.5 lpm 10 cm H_2O – 3.6 lpm 20 cm H_2O – 5.8 lpm 30 cm H_2O – 7.5 lpm 40 cm H_2O – 9.1 lpm	3 cm H_2O – 1.5 lpm 10 cm H_2O – 3.9 lpm 20 cm H_2O – 6.4 lpm 30 cm H_2O – 8.5 lpm 40 cm H_2O – 10.2 lpm
Internal volume / Dead space (measured)	N/A This mask covers the full face vs. nasal	N/A	120 ml	120 ml
Pressure Drop	0.08 cm H_2O @ 30 lpm 0.15 cm H_2O @ 60 lpm	N/A	0.25 cm H_2O @ 30 lpm 1.02 cm H_2O @ 60 lpm Tested with extension tube	0.31 cm H_2O @ 30 lpm 1.28 cm H_2O @ 60 lpm
Components	Headgear Shell / Cushion Swivel elbow	Headgear Shell / Cushion Swivel elbow	Headgear Shell / Cushion Swivel elbow	Headgear Shell / Cushion Swivel elbow
Materials	Tested to ISO 10993	Tested ISO 10993		Tested to ISO 10993

The IQ® Ventilation Nasal Mask is viewed as substantially equivalent to the predicate devices because:

Indications –

- Similar to - Respironics – Contour nasal mask (Deluxe) – K991648

Patient Population –

- Identical to SleepNet MoJo – K063806 and Respironics – Contour nasal mask (Deluxe) – K991648

Technology –

- Identical technology to – SleepNet IQ® Nasal mask – K021534

Materials –

- The materials in patient contact are identical to predicate device or have been tested per ISO 10993

Environment of Use –

- Identical to predicates – SleepNet MoJo – K063806 and Respironics – Contour nasal mask (Deluxe) – K991648

Differences –
There are no differences between the predicates and the proposed device.

Comparative Performance

We have performed comparative performance testing including – Pressure Drop, Unintentional leak, Internal volume / dead space, CO_2 rebreathing, and ISO 10993 biocompatibility testing.

The results demonstrated that the device is substantially equivalent to legally marketed predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Sleepnet Corporation
C/O Mr. Paul E. Dryden
President
Promedic, Incorporated
24301 Woodsage Drive
Bonita Springs, Florida 34134-2958

MAY 17 2011

Re: K102317
Trade/Device Name: IQ® Ventilation Nasal Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: May 11, 2011
Received: May 12, 2011

Dear Mr. Dryden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K102317

Device Name: IQ® Ventilation Nasal Mask

Indications for Use:

The IQ® Ventilation Nasal Mask is to be used as an accessory to CPAP / bi-level positive pressure systems that have adequate alarms and safety systems for positive pressure delivery failure. Use of this product is indicated for use with CPAP / BI-LEVEL POSITIVE PRESSURE SYSTEMS CONTAINING EXHALATION VALVES.

The IQ® Ventilation Nasal mask is intended for single patient, multi-use in the home environment and multiple patients, multi-use in the hospital/institutional environment.

Patient Population:
Adult patients (>30 kg)

Environment of Use:
Home or hospital / institutional environments.

Prescription Use XX (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use __** (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
)ivision of Anesthesiology, General Hospital
:ection Control, Dental Devices

10(k) Number: K102317